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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/666,722	09/18/2003	Lee Martin Greenberger	AM101032	9014

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WYETH
PATENT LAW GROUP
5 GIRALDA FARMS
MADISON, NJ 07940

EXAMINER	
BETTON, TIMOTHY E	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 11/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/666,722	GREENBERGER ET AL.	
	Examiner	Art Unit	
	Timothy E. Betton	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-81 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) 1-81 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-68 and 73-81 are drawn to a method of treating, inhibiting the growth of, or eradicating a tumor in a mammal in need thereof wherein said tumor is resistant to at least one chemotherapeutic agent which method comprises providing to said mammal an effective amount of a hemiasterlin compound of Formula (II), classified in class 514 and subclass 676. If this group is elected, then the below summarized specie elections are also required.

Group II. Claims 69-72 are drawn to a process for the preparation of a carboxylic acid of the said formula, classified in class 514 and subclass 676. If this group is elected, then the below summarized specie elections are also required.

Group I is distinct from Group II in that a method of treating and a process for preparation are disclosed respectively. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the

instant case, the inventions as claimed are distinct in that Group I is directed toward a practicing method of treating, inhibiting the growth of, or eradicating a tumor in a mammal. However, Group II is directed toward a process for the preparation of a carboxylic acid of disclosed formula. The Groups are related but distinct inventions in that they are not connected in at least one of: design, operation, or effect. In this instance, Groups I and II are distinct by design. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Because these inventions are distinct for the reasons given above and there would be a serious burden on the Examiner if restriction were not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

SPECIE ELECTION FOR GROUP I

Formula (II), Chemotherapeutic Agent, Tumor etiology/condition, Method/Regimen Specie Election for Group I

This application contains claims directed to the following patentably distinct species: Elect one exact and specific compound of Formula (II).

The species are independent or distinct because the claims encompass a multiplicity of chemical structure types, moieties, chemical formula names, etc., which are distinct one from the other. Instant claim 60 discloses an example of a selection of

a specific moiety. It would present an undue search burden on the Examiner because of such a multiplicity of species. Therefore, Applicant must elect one exact and specific compound of Formula (II).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-59 are generic to the above electable species.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Second Specie Election Requirement for Group I

This application contains claims directed to the following patentably distinct species: Elect one or an exact and specific chemotherapy agent/ antimicrotubule inhibitor or combination which will be administered with one electable Formula (II) compound. Examples are disclosed in instant claim 3 consisting of:

a) paclitaxel

b) docetaxel

c) vinblastine

d) vincristine

e) vinorebine

The species are independent or distinct because of various bioavailability factors, which distinguish one from the other. Additionally, a practicing co-administration with one antimicrotubule inhibitor species or a combination thereof with an electable compound of Formula (II) as disclosed presents such multiplicity in terms of susceptibilities and criteria for success. Such multiplicity would present an undue search burden on the Examiner. Therefore, Applicant must elect one exact and specific antimicrotubule inhibitor or a specifically named and clearly defined combination thereof.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-68 and 73-81 are generic to the electable species. The instant claims are directed specifically toward to an embodiment of antimicrobule inhibitors and a specific disclosure thereof (as listed above).

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Third Specie Election Requirement For Group I

This application contains claims directed to the following patentably distinct species: Elect one tumor disease/ condition, i.e., either breast, colon, lung, etc. The species are independent or distinct because of the differing etiologies and biochemical contributing factors associated with each same disease/condition. Instant claims 5-8 disclose examples of variations (e.g., tumor overexpression factors, resistance index/etiologies). Such multiplicity of factors would present an undue search burden on the Examiner. Therefore, Applicant must elect one exact and specific tumor disease/condition for examination.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-5, 7-55, 57-64, 66-68, 73-77, and 79-81 are generic to the above electable species. to the above electable species.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims

readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Fourth Specie Election Requirement for Group I

This application contains claims directed to the following patentably distinct species: Elect one regimen method specie according to instant claims 59, 68, and 81, i.e., determine specifically wherein the compound of Formula (II) will be given **a)** before, **b)** concurrently, or **c)** after treatment with the chemotherapeutic agent. The species are independent or distinct because of the significance of the variation of concomitant administration. These three combinations are distinct because of differing and variable bioavailability factors involved with each regimen method species of administration. As a result, it would present an undue search burden on the Examiner to examine all of these factors at one. Therefore, Applicant must elect one exact and specific regimen method species of administration.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-68 and 73-81 are generic to the above

electable species. Instant claims are drawn toward three embodiments of regimen therapy in terms of administration of said compound and antimicrotubule.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Additional Specie Election Requirement for Both Groups I and II

Regardless of which Group Applicant elects, Applicant is additionally required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Specifically, in Claim I applicant is required to define "treating" and the compounds and moieties that comprise such treatment. Applicant is required to define "inhibiting the growth of" and the compounds and moieties that comprise such inhibition of growth. Applicant is required to define "eradicating" and the compounds and moieties that comprise such eradication.

SPECIE ELECTION FOR GROUP II

Process of Preparation Specie Election for Group II

This application contains claims directed to the following patentably distinct species: Elect one exact and specific process for the preparation of a carboxylic acid of the disclosed formula in instant base claim 69. Elect one exact and specific chemical moiety (similar to claim 1 specie election) with R1-R8 constituents and all related constituents specifically named and defined. Elect one set of process steps as disclosed in claims 69 and 70 respectively. Further in instant claims 71 and 72, aqueous lithium hydroxide is disclosed as a base for both process steps of instant claims 69 and 70. Applicant must elect one exact and specifically defined process of preparation of a carboxylic acid of the disclosed formula. The species are independent or distinct because of the potential susceptibilities and criteria of success involved. This in turn would present an undue search burden on the Examiner. Therefore, Applicant must elect one clearly defined process of preparation of a carboxylic acid in accordance with instant invention.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 69 and 70 are generic to the above electable species.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that a reply to this requirement must include a proper identification of species that is elected consistent with this requirement, and a list of all claims readable thereon, including any claims that may be subsequently added. Any traverse that a claim is allowable or that all claims are generic is considered an improper and incomplete response unless accompanied by an election.

Upon the allowance of a generic claim, the Applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP§ 809.02 (a).

On the occasion Applicant traverses on the ground that the species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions

unpatentable over the prior art, the evidence may be used in a rejection under U.S.C. 103(a) of the other invention.

Election/Restrictions Proper

MPEP§ 809.02(d) states "[w]here only generic claims are presented, no restriction can be required except in those applications where the generic claims recite such a multiplicity of species that an unduly extensive and burdensome search is necessary." In this instant, the claims recite such a multiplicity of species that an unduly extensive and burdensome search would be necessary if all of the claimed species were to be examined simultaneously.

The present claims of Group I are drawn to a method of "treating, inhibiting the growth of, or eradicating a tumor". Treating doesn't necessarily mean inhibition of growth or vice-versa. The term eradication is unclear in the context of the claims. How is one able to determine eradication based on a compound used initially for treatment or inhibition of growth of a tumor? Present claim 1 provides a myriad of possibilities for R1, R2, R3, etc. Claim 59 does not clearly delineate a method of regimen of chemotherapeutic agent with said compound, i.e., the before, during, or after treatment.

Further, as shown by the following classifications, a majority of the combinations encompassed by the present claims has acquired a separate status. For example, Group II is drawn to the process of preparation of a carboxylic acid of the said compound. In addition to the various moieties to be examined in Group I, the co-extensive moieties of Group II would present an undue search burden on the Examiner.

Notwithstanding that the classification of some of the active agents is co-extensive and that all of the claimed compounds are patently distinct and fully capable of supporting separate patents.

For the above reasons, an election of a single disclosed species for examination purposes is deemed necessary and proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Inventorship Notice

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy E. Betton whose telephone number is (571) 272-9922. The examiner can normally be reached on Monday-Friday 8:30a - 5:00p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TEB

Ardin H. Marschel 11/17/06

ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER